



Student Manual



Lesson 6: Survey Process

Learning Objectives

At the conclusion of this lesson, you will be able to discuss:

- Procedures used to plan and conduct an ASC survey.
- Methods used to gather information before and during an ASC survey.
- The role of a surveyor.



Survey Process



Learning Objectives

At the conclusion of this lesson, you will be able to discuss:



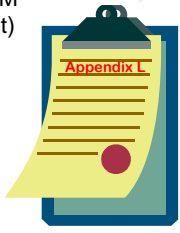
- Procedures used to plan & conduct an ASC survey
- Methods used to gather information before & during an ASC survey
- The role of a surveyor



2

ASC Survey Process General Information

Located in Appendix L of SOM
(separate reference handout)





3

Regulatory Basis

Survey Authority & Compliance Regulations



- 42 CFR 416 subpart B
- 42 CFR 422 subpart A
- Surveyors are required to use CMS Survey Process



4

Survey Team



- Within parameters established in SOM Appendix L, State Agency (SA) determines size & composition
 - RO determines for Federal survey
- Typically a standard, i.e., full survey should include 2 health standards surveyors and 1 Life Safety Code (LSC) surveyors onsite for 2 days
- At least 1 RN with ASC survey experience



5

Types of Surveys



- Initial surveys
 - ASC first seeks to participate in Medicare program
- Recertification surveys
 - Reconfirm ongoing compliance; at periodic intervals
- Validation surveys
 - Support CMS' oversight of national accreditation organizations (AOs)
 - Conducted by SA



6

Types of Surveys (cont.)

- Complaint
 - Determine the validity of an allegation of noncompliance; assess compliance with CfCs relevant to the substance of the allegation
- Onsite Revisit
 - Determine current compliance with CfCs that ASC was previously cited for noncompliance
- Such surveys are more narrowly focused than a full standard survey





7

Survey Process

Factors that affect the types & numbers of surveyors:



- Size of facility
 - Number of ORs
 - Hours of operation
 - Average monthly volume of cases
- Complexity of services offered
- Historical pattern of serious deficiencies/complaints
- Whether team includes surveyors in training



8

Application of Survey Process to Complaint Surveys


- Follows general format of survey process in SOM Appendix L
- Must survey entire CfC, not parts of CfC
- Usually only one surveyor
 - Selected based on knowledge of CfC to be reviewed
 - Decisions rely solely on one person observing, one person's skills and one person's judgment



9

Survey Team Coordinator



- **Critical role**
- Role assigned prior to survey by SA/RO
- Acts as the team "leader"
- Responsibility to ensure that survey activities are completed in a timely manner & in accordance with the State Operations Manual (SOM) & SA procedures
- Coordinating preparation of CMS Form 2567



10

Survey Team Coordinator (cont.)

- Other responsibilities include:
 - Scheduling the survey
 - Team spokesperson
 - Making assignments – who does what
 - Facilitating time management
 - Evaluating team progress



11

Survey Team Coordinator (cont.)

Facilitating

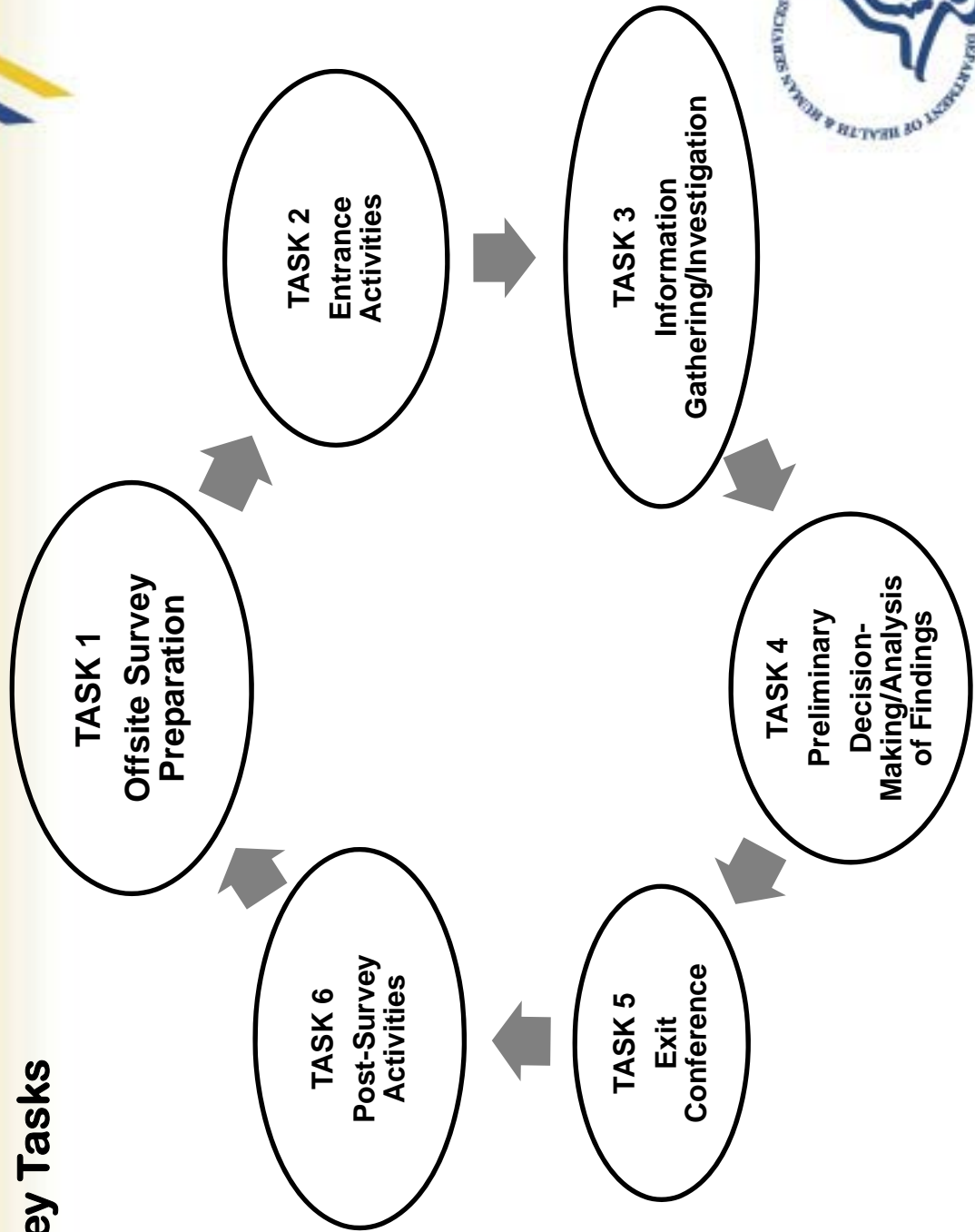
- Entrance conference
- Team meetings
- Preliminary decision making
- Exit conference



12



Organization of Survey Process

6 Survey Tasks



Task 1



Offsite Preparation



14

Task 1: Offsite Preparation



- Objectives:
 - Determine size and composition of survey team
 - Analyze information about ASC
 - Determine type of survey
 - Full/standard
 - Recertification
 - Complaint
 - Determine length of survey & number of surveyors necessary



15

Background Information



- Data gathered from SA's files and/or CMS database include:
 - Basic characteristics: ownership, hours of operation, size, types of surgical services offered
 - Publicly available information on ASC
 - Web site
 - Media reports
 - Information on physical layout
 - LSC waivers
 - History and results of previous Federal and State surveys
 - Directions to ASC



16

Prep Team Meeting



- Offsite survey prep team meeting – discuss:
 - Date & time of entrance
 - Areas of potential concern to be investigated during the survey
 - Preliminary team assignments
 - Questions about evaluation of CfCs
 - Time of daily team meetings
 - Potential exit date & time



17

Useful Resources



- Resources that may be needed during survey:
 - Appendix L – Guidance for Surveyors: ASCs
 - Appendix I – Survey procedures & logs for LSC surveys
 - Immediate Jeopardy (Appendix Q)
 - Copies of 42 CFR 1001.130 (failure to permit survey)



18

Task 2




Entrance Activities



19

Task 2: Entrance Activities




- Objectives:
 - To explain survey process to the ASC staff
 - To obtain information that is necessary for the survey from the ASC



20




Arrival



- Team should enter facility together
- Don't wait if CEO, etc. not present
- Survey is unannounced



21

Arrival (cont.)



- Be prepared! 
- Be courteous!  
- Make requests, not demands



22

Entrance Conference



- Discuss:
 - Purpose and scope of survey
 - Survey process
 - Introduce survey team
 - Interviews with staff & patients will be private
 - Clarify that all areas of ASC will be surveyed
 - Will not interfere with provision of care



23

Entrance Conference (cont.)



- Discuss:
 - Provision of photocopies in a timely manner
 - Names, locations, phone numbers of key staff and their responsibilities
 - Time, location, possible attendees of any meetings to be held
 - Proposed preliminary date and time for exit conference



24

Requested Information



- Arrange with ASC administrator to obtain:
 - List of all surgeries scheduled
 - List of surgeries from past 6 months and transfer cases from past year
 - Secure place for team to meet
 - Organizational chart
 - Selected policies and procedures



25

Requested Information (cont.)

- Obtain:
 - Selected personnel records
 - Documentation of infection control program
 - List of contracted services
 - Copy of facility's floor plan
 - Contact info for ASC leadership (e.g., department heads, managers, etc.)



26

Initial Onsite Meeting



- Held immediately after entrance conference
- Discuss any new information
- As needed, revise survey plan based on new information
- Revise assignments as needed



27

Task 3

Information Gathering/Investigation





28

Task 3: Information Gathering/Investigation

Objective:



- Determine ASC's compliance with CfCs through:
 - Observation
 - Interview
 - Document review



29

Observations



- Observation, observation, observation
 - Assess what is present that should not be present
 - Assess what is not present that should be present
 - The term "what" includes equipment, people, activities, processes, documentation, policies, building structure, etc.



30

Information Gathering/Investigation



- Be **alert** & observe:
 - Patients
 - The environment
 - Interactions with patients
 - Medication security
 - Infection control



31

Case Tracer Methodology

- Surveyors required to follow at least one patient from admission, through surgery, recovery, to discharge
- Observe for compliance with multiple CfCs throughout, particularly transition points
- Able to assess many CfCs





32

Case Selection

- Type of ASC
- Consent
- Length of case



Best to observe a case on the initial day of the survey to see the true situation



33

Information Gathering/Investigation (cont.)



- Share findings with team at daily team meetings
- Cross-verify information
- Maintain an open dialogue with ASC staff
 - Facility meetings – Team Coordinator decides if and when facility meetings will occur
 - Team Coordinator represents team at these meetings



34

Information Gathering/Investigation (cont.)



- Interview patients (or family) about:
 - Their care
 - Knowledge of their surgery/procedure, care, discharge planning & rights
 - The quality of care
- Interview staff about:
 - Knowledge of the patient & care needs
 - For example, interview assigned RN regarding knowledge of their assigned patients
 - Important policy/compliance issues

35

Interviews – Formal Versus Informal



- Conduct informal interviews throughout survey
- Interview staff caring for patients
- Document:
 - Time & place
 - Full name & title of the person interviewed
- Don't ask leading questions
- Provide reassurances if necessary, but be truthful

36

Interviews with Staff



- Be very sensitive to staff time constraints
- Most staff don't have time for a sit-down interview
- Take advantage of opportunities when staff are charting to ask 1 or 2 quick questions
- Open-ended questions (e.g., "What do you plan to do with Mr. Jones today?") can provide valuable information

37

Interviews with Staff (cont.)

- When observing something that “appears” incorrect, with which the surveyor is unfamiliar, or where the surveyor has questions
- Do **not** assume it’s wrong!
- Ask staff – “Tell me about this”, “Show me that policy, law, regulation or standard of practice”



38

Interviews with Staff (cont.)



- Be careful not to overwhelm or frighten staff
- Increasing staff comfort levels with surveyor presence can pay big dividends in information they may share with you
- Remember, care of the patient **comes first**
- Don’t get in the way of care provision



39

Interviews with Patients



- Be sensitive to their physical condition
- Limit the time & the number of questions
- Conversational questions:
 - Are you receiving the care you need?”
 - “Do people wash their hands?”
- 1 or 2 questions at a time & several different times may work better



40

Information Gathering/Investigation (cont.)



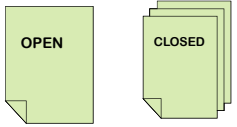
- Validate patient concerns during interviews with staff
- Allow the ASC an opportunity to provide additional information
- Review open records to validate concerns identified



41

Document Review



- Use open records whenever possible to determine compliance
- Closed records may be used to supplement



42

Documents



- May be written or electronic
 - Includes medical records
 - Personnel files
 - Maintenance records
 - Policies and procedures manuals
 - Contracts and transfer agreements



43

Sampling



- Cross-section of patient population & services offered
 - Including Medicare benes, deaths, transfers
- Use open records whenever possible
- Sample size
 - At least 20 records for facility with monthly case vol. > 50
 - Lower volume ASC – at least 10 records
 - Expand as needed



44

Complaint Surveys



- Review several closed records
- May need to observe open case
 - Depends on the CfCs to be surveyed for a complaint



45

Documentation



- Closed records may provide:
 - Verification
 - Wider scope
 - Information about past practices
- Closed records may be necessary if there are no patients in-house
- Review only the documents you need
 - The primary focus of the survey is **observation**



46

Surveyor Note Taking



- Photocopy all documents needed to support deficiency findings
- Photocopies – date, time, source
- Who, what, when, where, how, how many
 - Degree & manner
 - Prevalence & criticality
- Take notes on plain paper or any other note taking tool



47

Review of Policies & Procedures



- Only review those needed to make compliance determinations
- Use the P&P located at site of use (Nursing P&P at actual nursing unit)
 - Many ASC likely to have only one set of P&P
- Statements of findings based on P&P at site of use – **may not** be the same as the ones administration puts forth as the “correct” P&P



48

Electronic Records



- Same requirements as paper records
- Must always be accessible, retrievable & secure
- What happens when computer “goes down”
- More important that staff can prove they can use the system than whether the surveyor can use the system



49

Electronic Records (cont.)



- ASC staff must be able to demonstrate ability to access all parts of the record
- ASC staff must be able to print parts of record when requested by surveyors
- Surveyors must be provided access to electronic medical records. Either:
 - Provide terminal and tutorial to surveyor, or
 - Provide/allow staff person(s) to assist surveyor and access information as requested



50

Medical Records



- Surveyors should not request entire records merely because they wish to review a paper document
- A request for a printout/copy should be made based on the need for printed material to support findings



51

Task 4

Preliminary Decision Making & Analysis of Findings





52

Task 4: Analysis of Findings

Objective:

- To integrate findings, review & analyze all information collected from observations, interviews & document review & to determine whether the ASC meets the regulatory requirements





53

Prep/Discussion Meeting

Preparation & discussion meeting:



- Prior to the team meeting, all members should review their work individually & prepare to present their findings
- Proceed sequentially through all the requirements
- Decisions are made by the **team**



54

Analysis of Findings



- While the discussion of compliance includes the information in the Interpretive Guidelines, any noncompliance must be cited only to the CfC, not the guidelines
- Team must ensure findings are supported by adequate documentation of observations, interviews & document reviews & include any needed evidence such as photocopies



55

CfC Compliance



- Compliance
- Noncompliance
 - Condition-level
 - Standard-level



56

Using Team Judgment



- Surveyors use their team **judgment** to assess an ASC's compliance with the CfCs
- If noncompliance is found, survey team judgment is used to make a **preliminary determination** regarding the level of noncompliance
- The preliminary and final determinations must adhere to CMS regulations and policy



57

Citations of Noncompliance



- ONLY current noncompliance is cited (past noncompliance that has not been completely corrected prior to the survey and sustained, is current noncompliance)
- Past noncompliance that was corrected prior to the survey is not cited
- Any noncompliance observed or identified while on survey must always be cited



58

Onsite Corrections

- Noncompliance is cited even if an ASC “corrects” an area of identified noncompliance while the survey team is on site
- Corrections that occur during the survey do not change the citation level. Noncompliance is cited at the level at which it was identified (When the immediate threat is abated during survey the deficiency is cited at the condition level)





59

Citations of Noncompliance (cont.)

Citations of noncompliance can be based on:

- Adverse outcomes that have occurred or are likely to occur if noncompliance is not corrected
- Noncompliance with required processes
- Noncompliance with any requirements within the CfC or Standard








60

Citation Levels

Three levels of citations exist:



- Immediate Jeopardy
- Condition-level noncompliance
- Standard-level noncompliance



61

Immediate Jeopardy (IJ)



- IJ is always considered condition level noncompliance due to the severity and immediacy of the situation. ASC must take immediate actions to avoid an accelerated termination process
- IJ is documented on the CMS-2567
- The condition of participation tag is cited and IJ is recorded in the write-up
- Any tags impacted by noncompliance related to the IJ are cited
- ASC may have more than one IJ at the same time



62

Standard Level Citations



- Any noncompliance with any requirement/tag within a standard, is standard level noncompliance
- The citation of finding of noncompliance, even a single item of noncompliance, would be cited at the Standard Level if the level of noncompliance is determined not meet the criteria for citing at the condition level



63

Standard/Condition Level



- Based upon degree and manner, one or more Standard Level citations may rise to a Condition Level citation



64

Correct Level of Citation Is Critical



- To protect patients and the integrity of the survey process, every citation must be cited at the level supported by the evidence
- Over citing unjustly impacts the ASC
- Under citing does not ensure that the area of noncompliance is corrected, thus allowing an unacceptable situation to continue that may result in future patient harm



65

Regulation



- 42 CFR 488.26
- The decision as to whether there is compliance with a particular CfC depends upon the manner & degree to which the provider or supplier satisfies the various standards with each condition
- There does **not** have to be an adverse patient outcome for condition-level noncompliance
 - Example: Under IC CfC, if no designated professional responsible for infection control – condition is out



66

Task 5

Exit Conference





67

Task 5: Exit Conference

Objective:

- To inform the ASC staff of the team's **preliminary findings**





68

Exit Conference

The Team Coordinator – organizer



- ASC determines which ASC staff will attend
- Discuss ground rules
 - Not the setting for further info gathering
- Do not reveal identities of patients or staff
 - Do not provide crosswalk for specific patient or staff identifiers
 - There is no CMS requirement to provide the ASC a list of patient identifiers



69

Presentation of Findings



- Describe the preliminary findings
 - Avoid referring to data tag numbers
 - Do not identify deficiencies at condition- or standard-level — rather “requirement”
- Do not rank findings
- Discuss all deficiencies



70

Exit Conference (cont.)



- Discuss the process for Statement of Deficiency (SoD) & Plan of Correction (PoC)
- Audio or video recording
- Prompt departure



71

Plan of Correction (PoC)

- **Three options:**
 - Accept deficiencies and submit PoC
 - Record objections to deficiencies and submit PoC
 - Record objections, do not submit PoC; submit written arguments and documented evidence that deficiencies are invalid
 - The termination clock does not stop even though a PoC is not submitted or a ASC objects to the survey findings



72

Discontinuation



- Discontinuation of exit conference
 - Attorney representation
 - Evidentiary hearing
 - Hostile, intimidating environment



73

Task 6

Post-survey Activities





74

Task 6: Post-survey Activities

Objective:



- To complete the survey & certification requirements, in accordance with regulations at 42 CFR 488



75

General Procedures

- Timeline for completion of each step of process
- Complete Form CMS-2567 using Principles of Documentation
- Notification to ASC of survey results
- Additional survey activities as needed
- Compilation of documents for supplier's file





76

Summary

Survey process:

- Standard protocol: 6 tasks
- Makeup of the survey team
- Role of the survey team coordinator
- Survey all areas of the ASC





77

Summary (cont.)

Survey task considerations:

- Objectives
- Issues
- References
- Information-gathering techniques
- Documentation
- CMS forms & tools





78

Summary (cont.)

Survey tasks:



- Offsite preparation
- Entrance activities
- Information gathering/investigation
- Preliminary decision making & analysis of findings
- Exit conference
- Post-survey activities



79

Questions?

Thank you!



80



Student Manual

Lesson 7: Infection Control



Learning Objectives

At the conclusion of this lesson, you will be able to:

- Complete the Infection Control Surveyor Worksheet.
- Discuss infection control components of the survey tool.
 - Hand hygiene.
 - Injection practices.
 - Instrument reprocessing.
 - High-level disinfection.
 - Sterilization.
 - Environmental cleaning.
 - Point-of-care devices.



Infection Control in ASCs

Marilyn Dahl, CMS
&
Melissa Schaefer, M.D., CDC



Introduction



- Detailed slides reviewing the infection control regulatory requirements in the training manual but not part of today's presentation
- Oral presentation will focus on completing the Infection Control Surveyor Worksheet



2

Infection Control Worksheet



- Essential that SAs:
 - Complete all pertinent sections of the Worksheet for each ASC surveyed
 - Complete 1 & only 1 Worksheet for each survey
 - Promptly submit a completed Worksheet for each survey to CMS' contractor (details on hand-out)



3

Infection Control Worksheet



- Worksheets will be used for detailed analysis of ASC infection control practices by CMS and CDC
- Incomplete, inconsistent or inaccurate Worksheet data impacts the reliability of the results of analysis



4

Worksheet Part 1



- Q's 1 -14 & 20 – ASC characteristics
- Will help identify potential correlates of infection control practices – e.g. better compliance in larger ASCs? In single-specialty ASCs?
- **Complete as many as possible prior to survey**



5

ASC Characteristics Q's

- 1) ASC name:
- 2) Address:
- 3) 10-digit CMS Certification Number:
- 4) What year did the ASC open for operation? ____





6

ASC Characteristics Q's (cont.)

5) Please list date(s) of site visit:
(mm/dd/yyyy) to _____
(mm/dd/yyyy)

6) What was the date of the most recent
previous federal (CMS) survey:
(mm/dd/yyyy)





7

ASC Characteristics Q's (cont.)

7) Does the ASC participate in Medicare via
accredited "deemed" status?
 YES NO

Check yes only if the RO issued a Form CMS
2802 authorizing the survey

– Do not rely on what ASC reports





8

ASC Characteristics Q's (cont.)

7a) If YES, by which CMS-recognized
accreditation organization? (Check only
ONE):

- AAAHC
- AAAASF
- AOA
- TJC

• ASC may be deemed by more than 1 AO; if so,
choose the AO reflected on the Form CMS 2802





9

ASC Characteristics Q's (cont.)

7b) If YES, according to the ASC, what was the date of the most recent accreditation survey?
_____ (mm/dd/yyyy)

- Ask the ASC for the most recent survey date by the AO indicated in 7a





10

ASC Characteristics Q's (cont.)

8) What is the ownership of the facility?

- Physician-owned
- Hospital-owned
- National corporation (including joint ventures with physicians)
- Other (please specify)

- Ask the ASC which category fits best. Choose only one





11

ASC Characteristics Q's (cont.)

9) What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC). **Check only ONE:**

<input type="checkbox"/> Dental	<input type="checkbox"/> Orthopedic
<input type="checkbox"/> Endoscopy	<input type="checkbox"/> Pain
<input type="checkbox"/> Ear/Nose/Throat	<input type="checkbox"/> Plastic/reconstructive
<input type="checkbox"/> OB/Gyn	<input type="checkbox"/> Podiatry
<input type="checkbox"/> Ophthalmologic	<input type="checkbox"/> Other





12

ASC Characteristics Q's (cont.)

10) What *additional* procedures are performed at the ASC (Check all that apply)?

<input type="checkbox"/> Dental	<input type="checkbox"/> Orthopedic
<input type="checkbox"/> Endoscopy	<input type="checkbox"/> Pain
<input type="checkbox"/> Ear/Nose/Throat	<input type="checkbox"/> Plastic/reconstructive
<input type="checkbox"/> OB/Gyn	<input type="checkbox"/> Podiatry
<input type="checkbox"/> Ophthalmologic	<input type="checkbox"/> Other

• **Do not check the one checked in #9**



13



ASC Characteristics Q's (cont.)

11) Who does the ASC perform procedures on? (**Check only ONE**):

Pediatric patients only

Adult patients only

Both pediatric and adult patients



14

ASC Characteristics Q's (cont.)



12) What is the average number of procedures performed at the ASC **per month**? _____
Ask the ASC for this information

13) How many Operating Rooms (including procedure rooms) does the ASC have?:

of rooms _____

actively maintained _____

• *Ask the ASC, but verify through observation*





15

ASC Characteristics Q's (cont.)

14) Please indicate how the following services are provided (check all that apply):

Anesthesia	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___
Environment Cleaning	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___
Linen	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___
Nursing	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___
Pharmacy	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___
Steriliz./Reprocess.	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___
Waste Management	<input type="checkbox"/> Contract	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	___

- Ask the ASC for this information
- More than 1 may be checked for each service





16

ASC Characteristics Q's (cont.)

20) How many procedures were observed during the site visit:



1 2 3 4 Other



17

Worksheet Standard (b) Assessment

- Q's 15 – 19 related to ASC infection control CfC requirements
- Surveyors must validate responses; should not rely upon interview alone





18

**Worksheet Standard (b)
Assessment (cont.)**

15) Does the ASC have an explicit infection control program? YES NO

*NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.*

- *Explicit: e.g., written P&Ps, including guidelines selected, responsibilities, etc.*





19

**Worksheet Standard (b)
Assessment (cont.)**

16) Does the ASC's infection control program follow nationally recognized infection control guidelines? YES NO

*NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.*





20

**Worksheet Standard (b)
Assessment (cont.)**

16a) Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program? YES NO

- *NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51*





21

**Worksheet Standard (b)
Assessment (cont.)**

16b) Which nationally-recognized infection control guidelines has the ASC selected for its program (Check all that apply)?

- CDC/HICPAC Guidelines
 - Isolation Precautions
 - Hand Hygiene
 - Disinfection & Sanitation in Healthcare Facilities
 - Environmental Infection Control
- Periop. Standards & Recommended Practices (AORN)
- Specialty surgical society guidelines
- Other(s)





22

**Worksheet Standard (b)
Assessment (cont.)**

17) Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?

YES NO



*NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.*



23

**Worksheet Standard (b)
Assessment (cont.)**

- If the answer to #17 is "No", skip 17(a) – (d)
- Do not confuse the issue of whether the person running the infection control program is licensed with whether he/she is certified in infection control
 - *Must be a licensed healthcare professional, e.g., RN, but need not be infection control-certified*





24

**Worksheet Standard (b)
Assessment (cont.)**

If YES,
17a) is this person an: (check only ONE):

ASC employee
 ASC contractor





25

**Worksheet Standard (b)
Assessment (cont.)**

17b) Is this person certified in infection control (i.e., CIC) (Note: §416.50(b)(1) does **not** require that the individual be certified in infection control.)

YES NO

17c) If this person is **NOT** certified in infection control, what type of infection control training has this person received?





26

**Worksheet Standard (b)
Assessment (cont.)**

17d) On average how many hours per week does this person spend in the ASC directing the infection control program?



Note: §416.51(b)(1) does **not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)



27

**Worksheet Standard (b)
Assessment (cont.)**



18) Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC? YES NO



28

**Worksheet Standard (b)
Assessment (cont.)**

- 18a) If YES, how does the ASC obtain this information? (Check ALL that apply)
 - E-mails to patients after discharge
 - Follow up with patients' PCP
 - Relies upon reports from surgeon
 - Other





29

**Worksheet Standard (b)
Assessment (cont.)**

18b) Is there supporting documentation confirming this tracking activity?
 YES NO

*NOTE! If the ASC does not have an identification system, a deficiency related to 42 CFR 416.44(a)(3) and 42 CFR 416.51(b)(3) **must** be cited.*





30

**Worksheet Standard (b)
Assessment (cont.)**

18c) Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?
 YES NO



*NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to 42 CFR 416.44(a)(3). CMS does not specify the means for reporting; generally this would be done by the State health agency.*



31

**Worksheet Standard (b)
Assessment (cont.)**



19) Do staff members receive infection control training? YES NO
If YES,
19a) How do they receive infection control training (check all that apply)?
 In-service
 Computer-based training
 Other (specify)



32

**Worksheet Standard (b)
Assessment (cont.)**

19b) Which staff members receive infection control training? (**check all that apply**):
 Medical staff
 Nursing staff
 Other staff providing direct patient care
 Staff responsible for on-site sterilization/high-level disinfection
 Cleaning staff
 Other (specify):





33

**Worksheet Standard (b)
Assessment (cont.)**

19c) Is training:

- The same for all categories of staff
- Different for different categories of staff





34

**Worksheet Standard (b)
Assessment (cont.)**

19d) Indicate frequency of staff infection control training (check all that apply):

- Upon hire
- Annually
- Periodically/as needed
- Other (specify):





35

**Worksheet Standard (b)
Assessment (cont.)**

19d) Is there documentation confirming that training is provided to all categories of staff listed above? YES NO



*NOTE! If training is not provided to appropriate staff upon hire/granting of privileges with some refresher training thereafter, a deficiency **must** be cited in relation to 42 CFR 416.51(b) and (b)(3). If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.*



36

Worksheet Part 2



- Tool for assessing compliance with Standard (a) – i.e., that the ASC provides a functional and sanitary environment by adhering to professionally acceptable standards of practice



37

CMS Citation Instructions



- CMS also added the citation instructions on Part 2 of the worksheet
- Unless otherwise indicated in the body of the worksheet (highlighted in yellow), a “No” response to any question in Part 2 must be cited as a deficient practice in relation to 42 CFR 416.51(a).



38

Worksheet Part II



- Dr. Schaefer will discuss how to complete Worksheet & assess infection control practices
- Remainder of slides following on ASC infection control CfCs are for future reference



39

Infection Control CfC



- §416.51 consists of:
 - Condition statement
 - 2 Standards
- §416.44(a)(3) also retained



40

Condition



- §416.51: *The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.*



41

ASC Infection Control Challenges



- Patients in common areas
- Surgical prep, recovery rooms and ORs turned around quickly for multiple patients



42

ASC Infection Control Challenges (cont.)



- Patients entering with communicable diseases may not be identified
- Surgical site infection risks



43

ASC Infection Control Challenges (cont.)



- Patient short stay makes identifying infections associated with the ASC harder
 - Requires gathering information after the patient's discharge rather than directly



44

Why Emphasize?



- Consequences of poor infection control can be very serious
 - Poor practices in some ASCs exposed thousands of patients potentially to hepatitis C or HIV
- CMS pilot suggests lax practices widespread in ASCs



45

Standard (a)



- *“The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.”*



46

Standard (a) (cont.)



- Part 2 of infection control surveyor worksheet provides detailed guidance for assessing whether an ASC maintains a sanitary environment & adheres to standards of practice



47

Standard (b)

- *“The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is –*





48

Standard (b) (cont.)

(1) *Under the direction of a designated and qualified professional who has training in infection control;*



(2) *An integral part of the ASC's quality assessment and performance improvement program; and*



49

Standard (b) (cont.)



(3) *Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement."*



50

§416.44(a)(3)



- *"The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities."*



51

Guidelines



- ASC must select nationally recognized guidelines to be used for its infection control program
 - CMS does **not** prescribe specific guidelines
 - ASC must document its choice(s)



52

Examples – Guidelines



- CDC/HICPAC (www.cdc.gov/ncidod/dhqp/guidelines.html)
 - Isolation Precautions
 - Hand Hygiene
 - Surgical Site Infection Prevention
 - Disinfection and Sterilization in Healthcare Facilities
 - Environmental Infection Control in Healthcare Facilities



53

Guideline Sources

- AORN Perioperative Standards & Recommended Practices
 - www.aorn.org/PracticeResources/AORNStandardsAndRecommendedPractices/
- Guidelines issued by specialty surgical society/organization – ASC must identify
- Others – ASC must identify



54

Program Leadership



- Health care professional, qualified by training in infection control
 - *Certification desirable, but not required*
 - *Ongoing training required to maintain competency*
- ASC must designate infection control program's director in writing



55

Program Leadership (cont.)

- Leadership must be on-site
 - *National chain corporate infection control director OK, but not sufficient*
 - *Consultant may be used*
 - *On-site time not specified; must be sufficient to ASC's program size*





56

Program Components

Components of ongoing program to prevent, control, and investigate infections/communicable diseases:



1. *Development and implementation of infection control activities related to ASC personnel, i.e., all ASC medical staff, employees, and on-site contract workers (e.g., housekeeping staff, etc);*



57

Program Components (cont.)



2. *Mitigation of risk of healthcare-associated infections (HAIs);*
3. *Identifying infections;*



58

Program Components (cont.)



4. *Monitoring infection control program compliance; and*
5. *QA/PI – program evaluation and revision of the program, when indicated*



59

Personnel-related Activities



- Training in methods to prevent exposure to and transmission of infections
 - *New staff*
 - *Regular updates*



60

Personnel-related Activities (cont.)



- Policies governing:
 - *Screening*
 - *Limiting direct patient care*



61

Risk Mitigation



- Surgery-related measures:
 - *Appropriate prophylaxis to prevent surgical site infection (SSI)*
 - *Aseptic technique practices*



62

Risk Mitigation (cont.)



- Other ASC HAI measures:
 - *Hand hygiene*
 - *Safe practices for injecting medications and saline or other infusates;*



63

Risk Mitigation (cont.)



- Other ASC HAI measures:
 - Use of facility & medical equipment, e.g., air filtration equipment, UV lights, to control the spread of infectious agents
 - Appropriate sterilization or high-level disinfection of instruments/equipment



64

Risk Mitigation (cont.)



- Other ASC HAI measures:
 - Using disinfectants and germicides per manufacturers' instructions
 - Educating patients and visitors about infections and communicable diseases and methods to reduce transmission



65

Identifying Infections



- Infection detection through ongoing data collection and analysis
 - includes patient follow-up for HAI after discharge
 - May delegate to ASC physicians who see the patients post-discharge, if the results of the follow-up are reported back to the ASC and documented in the medical record



66

Monitoring Compliance



- ASC must document, including measures selected, and collection and analysis methods
- Infection control program must have ongoing system to monitor internal compliance with guidelines, policies & procedures



67

QAPI



- Infection control data and program activities are ongoing part of the ASC's QAPI program
- ASC must take immediate action in response to data analyses that ID areas needing improvement



68

Infection Control Resources



- QAPI regulation at §416.43(e)(5) requires ASC to allocate sufficient staff, time, information systems and training for QAPI
- This includes the ASC's infection control program



69

State Reporting



- If the ASC is subject to reporting incidents of specified communicable diseases under State law, it must comply per §416.42(a)(3)



70

Assessing Compliance



- Infection control surveyor worksheet – detailed assessment tool
 - Includes citation instructions
- Focused on infection control basics; does not preclude surveyor assessment of other areas of infection control



71

Assessing Compliance (cont.)



- Part 2 of Worksheet: Standard (a), i.e., do ASC practices conform to infection control standards
- Part 1 of Worksheet: most of Standard (b), i.e., program organization & leadership



72



**Assessing
ASC Infection Control
Practices**

Melissa Schaefer, MD
Division of Healthcare Quality Promotion
Centers for Disease Control and
Prevention





Nevada Outbreak

- January, 2008, Southern Nevada Health District and CDC investigated cluster of acute hepatitis C virus infections linked to endoscopy clinic



Infection Control Deficiencies

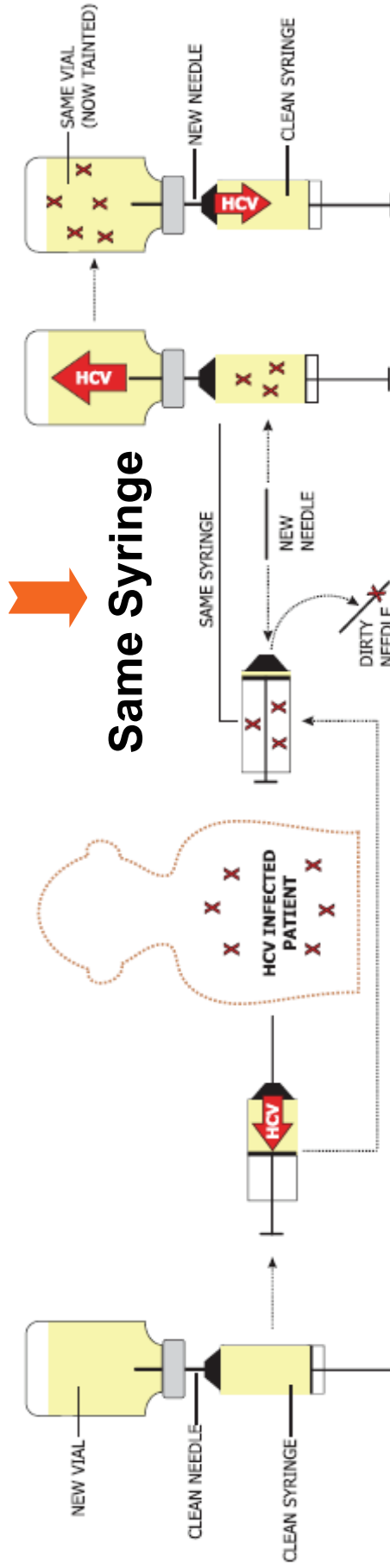
- 2 breaches in injection safety likely led to transmission
 - Re-entering medication vials with used syringe
 - Using single-dose medications on more than one patient



Unsafe Injection Practices Disease Transmission

Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.



1. A clean syringe and needle are used to draw the sedative from a new vial.

2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.



3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.

4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.



Outcome of the Investigation



- Syringe reuse was long-standing practice by 2 CRNAs at the facility
- Over 50,000 former patients were notified of potential exposure to infectious diseases
- Infection control notice sent to State's ASCs
- Led to call to inspect all 51 of the State's ASCs
 - Emphasis on evaluation of infection control



5

Infection Control Assessment in Nevada ASCs



- Focused effort of all of the State's surveyors
- Utilized instrument to focus surveyor attention on key areas of infection control
- CDC and infection preventionists from APIC assisted surveyors



6

Nevada 2008 ASC Surveys



- Federal surveys conducted in 28 of the 51 Nevada ASCs
- 64% had condition-level problems
 - 18% (5 ASCs) terminated



7

ASC Pilot - FY 2008



- Maryland, North Carolina, Oklahoma
- Total of 68 ASCs surveyed
- Identified widespread deficiencies, particularly in infection control



8

Feedback from Nevada and Pilot States

- Various levels of comfort with infection control assessments
- Survey tool was helpful resource to key areas where they should focus attention
- Wider implementation of infection control survey tool





9

Objectives

At the conclusion of this lesson, you will be able to:



- Discuss infection control components of the survey tool
 - Hand hygiene
 - Injection practices
 - Instrument reprocessing
 - High-level disinfection
 - Sterilization
 - Environmental cleaning
 - Point-of-care devices



10

Infection Control Survey Tool



- Part 1
 - Facility demographics
 - Questions to assess facility compliance with maintaining an infection control program
 - Often answered by facility administrator



11

Infection Control Survey Tool (cont.)



- Part 2
 - Questions related to core components of infection control
 - Reminders on where to focus attention
 - Focuses on observation of ASC staff



12

Infection Control Survey Process

- Emphasis on observations
 - Supplement with interviews
- Focus on staff who perform procedures
 - Injection practices → Nurses
Physicians
 - Instrument reprocessing → Reprocessing technicians





13

**Infection Control
Survey Process (cont.)**

- Circle responses
- If N/A circled, surveyor should explain
- Comments and additional breaches at end of each core section

Practice assessed	Was practice performed?	Manner of confirmation
Needles are used for only one patient	(Yes) No N/A	Observation Interview (Both)



14

Hand Hygiene

I. Hand Hygiene



Additional Instructions:

- **Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.).** Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Practices to be Assessed	Was practice performed?	Manner of confirmation
A. All patient care areas have: Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is "No." a. Soap and water available b. Alcohol-based hand rubs available I. If alcohol-based hand rub is available in patient care areas, it is installed as required	Yes No Yes No Yes No	Observation Interview Both Observation Interview Both There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs

Hand Hygiene (cont.)



- Cornerstone of infection control
- Single most effective method to prevent the spread of communicable disease
- Includes
 - Hand washing: use of plain or antimicrobial soap and water to remove microorganisms and soil
 - Use of waterless hand gel to clean hands



16

Hand Hygiene (cont.)



- Soap and water
 - Always used when hands are visibly soiled
- Alcohol-based hand rub
 - At least 60% ethanol or isopropanol
 - Can be used for routine disinfection of hands except when visibly soiled



17

Hand Hygiene (cont.)

- Observations in patient-care areas
 - Pre-operative area
 - Post-operative area
- Focus on:
 - Nurses
 - Physicians



18

Hand Hygiene Adherence

- Challenging to assess
- Focus on high-risk activities
 - After direct patient contact
 - After removing gloves
 - Before performing invasive procedures
 - After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)

Page 7 of Survey Tool

b. Staff perform hand hygiene:							
a. After removing gloves	Yes	No	N/A	Observation	Interview	Both	
b. After direct patient contact	Yes	No	N/A	Observation	Interview	Both	

19

Gloves

- Healthcare providers should wear (non-sterile) gloves:
 - For procedures that might involve contact with blood or body fluids
 - When handling potentially contaminated patient equipment

20

Gloves (cont.)

- Healthcare providers should remove gloves (and immediately perform hand hygiene) before moving to the next task and/or patient

Page 8 of Survey Tool

c. Regarding gloves, staff:							
a. Wear gloves for procedures that might involve contact with blood or body fluids	Yes	No	N/A	Observation	Interview	Both	

21

Injection Practices

Page 8 of Survey Tool

II. Injection Practices (injectable medications, saline, other infusates)



Additional Instructions:

Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Practices to be Assessed	Was practice performed?	Manner of confirmation
A. Needles are used for only one patient	Yes No N/A	Observation Interview Both
B. Syringes are used for only one patient	Yes No N/A	Observation Interview Both
C. Medication vials are always entered with a new needle	Yes No N/A	Observation Interview Both
D. Medication vials are always entered with a new syringe	Yes No N/A	Observation Interview Both
E. Medications that are pre-drawn are labeled with the medication name, strength, and expiration date or time Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs	Yes No N/A	Observation Interview Both

Injection Safety (cont.)



- Observations in patient care and medication preparation areas
 - Pre-operative area
 - Operating/Procedure rooms
 - Anesthesia cart
- Focus on:
 - Nurses (e.g., RN, CRNA)
 - Physicians (e.g., anesthesiologists)



23

Injection Safety (cont.)



- Needles are used for **only one** patient
- Syringes are used for **only one** patient
- Medication vials are **always** entered with:
 - New needle
 - New syringe



24

Pre-drawing Medications



- If medications are pre-drawn, they are labeled with:
 - Date/time the medication was drawn
 - Initials of person drawing
 - Medication name
 - Strength (mg/ml)



25

Single-dose and Multi-dose Medications

- Single-dose medications
 - One patient
 - One procedure
- Multi-dose medications
 - Ideally dedicated to one patient
 - If used for more than one patient, must follow strict parameters



26

Single-dose Medications


F.	<p>a. Single dose (single-use) medication vials are used for only one patient (A "No" response must be cited in relation to 42 CFR 416.48(a).)</p>	<p>Yes No N/A</p>	<p>Observation Interview Both</p>	
	b.	<p>Manufactured prefilled syringes are used for only one patient</p>	<p>Yes No N/A</p>	<p>Observation Interview Both</p>
	c.	<p>Bags of IV solution are used for only one patient</p>	<p>Yes No N/A</p>	<p>Observation Interview Both</p>
	d.	<p>Medication administration tubing and connectors are used for only one patient</p>	<p>Yes No N/A</p>	<p>Observation Interview Both</p>

Page 9 of Survey Tool

Handling of Single-dose Medications and Supplies

- Single-dose medication vials
- Manufacturer-prefilled syringes
- Bags of IV solution
- Medication administration tubing and connectors


All used for a single patient only!



CMS

Medications Used for Multiple Patients

Identify medications commonly used for multiple patients



G. List all injectable medications/infusates that are in a vial/container used for more than one patient:

Name of Medication	Average number of patients per vial/container

Page 9 of Survey Tool

Multi-dose Medications

<p>H. Multi-dose injectable medications are used for only one patient (Note: a "No" answer here is not necessarily a breach in infection control and does not result in a citation. However, a "No" response to the related questions I – K should be cited.)</p>	<p>Yes No N/A</p>	<p>Observation Interview Both</p>
---	-------------------	-----------------------------------

Page 9 of Survey Tool

A "No" answer is not necessarily a breach in infection control.




Circle N/A if no multi-dose medications/infusates are used.)

If YES, please skip to "L"
 If NO, please answer "I-K":



Handling of Multi-dose Medications





- If used for more than one patient:
 - Rubber septum is disinfected with alcohol prior to each entry
 - Vials are dated when opened and discarded within 28 days or according to manufacturer instructions, whichever comes first
 - Vials are not stored or accessed in the immediate areas where direct patient contact occurs (e.g., at patient bedside)



31

Sharps Disposal

- Sharps are disposed of in a puncture-resistant sharps container
- Sharps containers replaced when fill line is reached



32

Single-use Devices, Sterilization and High-level Disinfection

Page 10 of Survey Tool

III. Single Use Devices, Sterilization, and High-level Disinfection



Additional instructions:

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

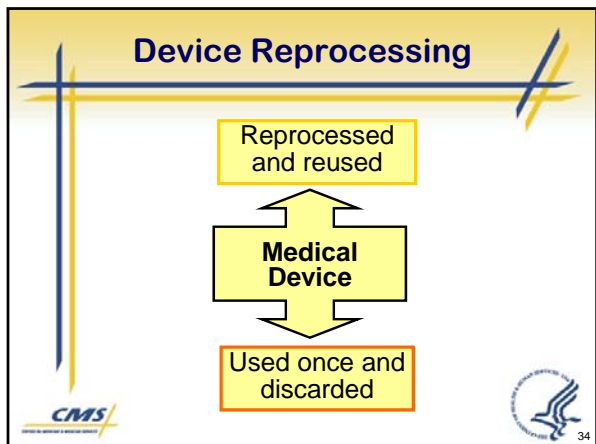
Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

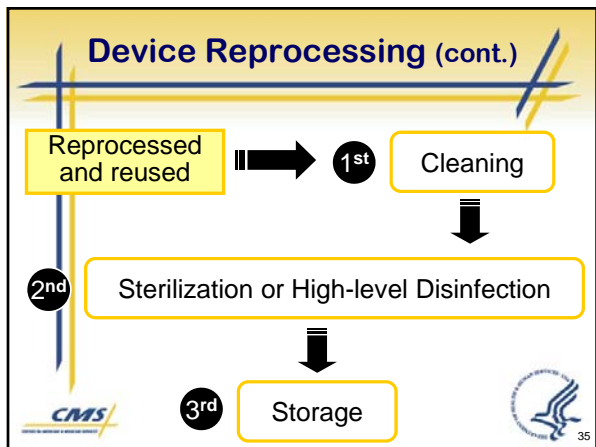
High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.



33







- ### Categories of Reprocessed Equipment
- Spaulding Classification
 - Critical devices: items that enter normally sterile tissue or the vascular system
 - Surgical instruments
 - Semicritical devices: items that come in contact with non-intact skin or mucous membranes.
 - Endoscopes
 - Laryngoscope blades
- The CMS logo and a bird logo are in the bottom corners.

Categories of Reprocessed Equipment (cont.)



- Spaulding Classification (cont.)
 - Noncritical devices: items that come in contact with intact skin but not mucous membranes
 - Blood pressure cuffs, pulse oximeter



37

Equipment Reprocessing



- Observations in:
 - Reprocessing room
 - Clean storage room
- Focus on:
 - Reprocessing technician
 - Surgical technician
- Check:
 - Log books



38

Equipment Reprocessing (cont.)



- Adherence to manufacturer's instructions
 - Equipment
 - Chemicals
- Education and competency of employees reprocessing the equipment



39

1st Cleaning

- Performed with:
 - Detergent and water
 - Enzyme cleaner and water
- Must be performed:
 - As soon as possible after use
 - Prior to sterilization or disinfection
- Removes bioburden and foreign material that can interfere with sterilization or high-level disinfection process



40

2nd Sterilization



Practices to be Assessed	STERILIZATION		Manner of confirmation
	Was practice performed?		
	Yes	No	Both
<p>A. Critical equipment is sterilized</p> <p>B. Are sterilization procedures performed on-site? (If NO, Skip to "F")</p> <p><i>(A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)</i></p> <p><i>(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)</i></p> <p>IF YES, Please indicate method of sterilization.</p> <p><input type="checkbox"/> Steam autoclave</p> <p><input type="checkbox"/> Peracetic acid</p> <p><input type="checkbox"/> Other (specify): _____</p> <p>C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization</p>	N/A	N/A	Both
	Yes	No	Both

Page Break



2nd Sterilization (cont.)



- All critical equipment must be sterilized
- Examples of sterilization techniques:
 - Steam autoclave
 - Peracetic acid
 - Ethylene oxide
 - Hydrogen peroxide gas plasma



42

Sterilization (cont.)



- Sterilization processes must be cleared by FDA and ASCs should follow manufacturer's instructions
 - Cleaning
 - Packaging
 - Loading
 - Monitoring (mechanical, chemical, biological indicators)
 - Storage



43

Sterilization (cont.)



- Chemical indicator
 - Indicates item has been exposed to the sterilization process
 - Performed with every load
- Biologic indicator
 - Directly monitors lethality of sterilization process
 - Performed at least weekly and with all loads containing implantable devices



44

Sterilization (cont.)



- Mechanical indicator
 - Monitors the sterilization process (e.g., time, temperature and pressure)
- Recommended documentation includes:
 - Contents of each load
 - Results of mechanical, chemical and biological monitoring



45

3rd Storage and Handling



- Items should be handled and contained during sterilization process to assure sterility not compromised prior to use



46

“Flash” Sterilization

- Traditionally referred to a **short** sterilization cycle for a small and **unwrapped** load
 - Concern about maintaining sterility after removal from sterilizer because device unwrapped
- Should not be routine practice
 - Appropriate for urgent and/or unpredicted need (e.g., instrument is dropped)



47

Assessing "Flash" Sterilization



- What does the facility mean when they say "flash"?
- What cycles does the facility run?
- Refer to manufacturer's instructions
 - Is sterilizer labeled for this cycle by the manufacturer?
 - What is the recommended load for that cycle?
 - Is the containment device labeled for use in that cycle? With that load?
 - Is chemical indicator labeled for use in that cycle?
 - Is the cycle checked regularly with a biological indicator and is the biological indicator labeled for use with that cycle?



48

3rd Storage and Handling

- Sterile items should be stored in a clean area so sterility is not compromised
- Sterile packages should be inspected to assure integrity



49

2nd High-level Disinfection



HIGH-LEVEL DISINFECTION		Manner of confirmation
Practices to be Assessed	Was practice performed?	
A. Semi-critical equipment is high-level disinfected or sterilized	Yes No N/A	Observation Interview Both
B. Is high-level disinfection performed on-site? (If NO, Skip to "F") (A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)	Yes No N/A	Observation Interview Both
<p>If YES. Please indicate method of high-level disinfection.</p> <p><input type="checkbox"/> Manual</p> <p><input type="checkbox"/> Automated</p> <p><input type="checkbox"/> Other (specify): _____</p>		Observation Interview Both

Page 13 of Survey Tool



2nd High-level Disinfection (cont.)



- All semi-critical equipment must be high-level disinfected (at a minimum)
- High-level disinfection can be:
 - Manual
 - Automated (e.g., Automated Endoscope Reprocessor – AER)



51

High-level Disinfection (cont.)



- High-level disinfection processes must be cleared by FDA and ASCs should follow manufacturer's instructions
- Endoscope reprocessing
 - Leak test
 - Clean
 - Disinfect
 - Rinse
 - Dry



52



High-level Disinfection (cont.)




- High-level disinfection equipment should be maintained according to manufacturer instructions
- Chemicals for high-level disinfection must:
 - Be prepared appropriately
 - Be tested for appropriate concentration
 - Be replaced appropriately
 - Have documentation of preparation and replacement



53

High-level Disinfection (cont.)

- Equipment subjected to high-level disinfection is:
 - Disinfected for an appropriate length of time 
 - Disinfected at an appropriate temperature 
 - Allowed to dry before use
 - Stored in a designated clean area

   54

Reprocessing Single-use Devices

SINGLE-USE DEVICES		
Practices to be Assessed	Was practice performed?	Manner of confirmation
<p>A. If single-use devices are reprocessed, they are devices that are:</p> <p>a. Approved by the FDA for reprocessing</p> <p>b. Reprocessed by an FDA-approved reprocessor.</p> <p>(Choose N/A if single-use devices are never reprocessed and used again)</p> <p>(Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)</p>	<p>Yes No N/A</p> <p>Yes No N/A</p>	<p>Observation Interview Both</p> <p>Observation Interview Both</p>

Page 11 of Survey Tool





Reprocessing Single-use Devices (cont.)

- If reprocessed, single-use devices are:
 - Approved by the FDA for reprocessing
 - Sent to an FDA-approved reprocessor
- <http://www.fda.gov/cdrh/reprocessing/>

List of Single-Use Devices Known To Be Reprocessed or Considered for Reprocessing (Attachment 1)

Note: This list includes all devices that FDA historically believed either were being reprocessed or were being considered for reprocessing. It is not a current list of devices known to be reprocessed in the United States today. For a listing of devices currently being reprocessed, see FDA's web page to search for "[Cleared/Reprocessed Single-Use Devices](#)" or search FDA's device "[Listing](#)" database.



56

Environmental Cleaning (cont.)

IV. Environmental Infection Control

Additional Instructions:



Observations are to be made of staff who perform environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

Page 15 of Survey Tool

Practices to be Assessed	was practice performed?	Manner of confirmation
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	Yes NO N/A	Observation Interview Both
B. Operating rooms are terminally cleaned daily	Yes NO N/A	Observation Interview Both
C. High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant	Yes NO N/A	Observation Interview Both
D. The ASC has a procedure in place to decontaminate gross spills of blood	Yes NO N/A	Observation Interview Both
E. Additional breaches in environmental cleaning not captured by the questions above were identified (if YES, please specify further in comments)	Yes NO N/A	Observation Interview Both

Environmental Cleaning (cont.)



- Observation in:
 - Operating/procedure rooms
 - Pre-operative area
 - Post-operative area
- Focus on:
 - Surgical technicians
 - Nurses



58

Environmental Cleaning (cont.)



- Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant
- Operating rooms are terminally cleaned daily
 - Performed at completion of daily schedule
 - Cleaning of all surfaces, including floor



59

Environmental Cleaning (cont.)

- High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant
- Facility has a procedure to decontaminate gross spills of blood



60

Point of Care Devices

Page 15 of Survey Tool

V. Point of Care Devices (e.g., glucometer)

Additional instructions:



Observations are to be made of staff who perform fingerstick testing (e.g., nurses)

Practices to be Assessed	Was practice performed?	Manner of confirmation
Does the ASC have a <u>Glucometer</u> ? Yes ___ No ___ (If NO, STOP HERE)	Yes No N/A	Observation Interview Both
A. A new single-use, auto-disabling lancing device is used for each patient	Yes No N/A	Observation Interview Both
B. The <u>glucometer</u> is not used on more than one patient unless the manufacturer's instructions indicate this is permissible.	Yes No N/A	Observation Interview Both
C. The <u>glucometer</u> is cleaned and disinfected after every use.	Yes No N/A	Observation Interview Both
D. Additional breaches in appropriate use of point of care devices (like <u>glucometers</u>) not captured by the questions above were identified (If YES, please specify further in comments)	Yes No N/A	Observation Interview Both

Comments:

Point of Care Devices (cont.)



- Diagnostic testing at or near the site of patient care
 - Blood glucose monitors
 - Portable INR monitor



62

Point of Care Devices (cont.)



- Observation in:
 - Pre-operative area
 - Post-operative area
- Focus on:
 - Nurses



63

**Glucose Testing
Fingerstick Devices**



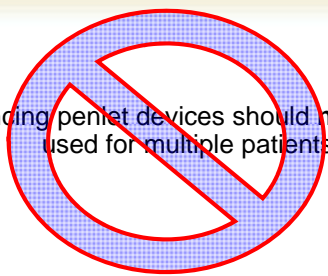
- A new single-use, auto-disabling lancing device is used for each patient



64

Glucose Testing Fingerstick Devices (cont.)

Lancing penlet devices should **not** be used for multiple patients



65

Blood Glucose Monitors

- Blood glucose monitor is not used on more than one patient unless manufacturer's instructions indicate this is permissible
- Blood glucose monitor is cleaned and disinfected after every use








Image courtesy of FDA



66

Summary



- Survey tool meant to focus on key aspects of infection control
 - Not exhaustive list
 - Breaches not identified by the tool still important and worthy of notation
- CMS and CDC will be analyzing survey tools
 - Identify common breaches
 - Target prevention strategies



67

Surveyor Feedback



- Convey feedback through supervisors or written comments on the tool regarding:
 - Areas that warrant additional questions or explanations
 - Introduction of new sections



68

Resources



- Disinfection and Sterilization
 - http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf
- Environmental Cleaning
 - http://www.cdc.gov/ncidod/dhqp/gl_enviroinfection.html
- Hand Hygiene
 - http://www.cdc.gov/ncidod/dhqp/gl_handhygiene.html



69

Resources (cont.)



- Isolation Precautions
 - http://www.cdc.gov/ncidod/dhqp/gl_isolation.html
- Injection Safety
 - <http://www.cdc.gov/ncidod/dhqp/injectionsafety.html>
- Glucometers
 - <http://www.cdc.gov/hepatitis/Populations/GlucoseMonitoring.htm#section1>



70

Disclaimer



The findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention



71

Questions?

Thank You!



72
